

## REMARKS

Applicants note that all amendments, cancellations, and additions of Claims presented herein are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),<sup>1</sup> and without waiving the right to prosecute the cancelled claims (or similar claims) in the future.

In the Final Office Action mailed 11/28/03 and the Appeal 2007-2708, there were three outstanding rejections: 1) Claims 1-4 and 11 are allegedly anticipated under 35 U.S.C. § 102(b) by Manautou *et al.* (U.S. Patent No. 3,875,013); 2) Claims 5-6, 8-15, and 18-27 are allegedly obvious under 35 U.S.C. § 103(a) in light of Manautou *et al.* in view of Bogema (U.S. Patent No. 6,248,598); and 3) Claim 7 is allegedly obvious under 35 U.S.C. § 103(a) in light of Manautou *et al.* in view of Kindler (U.S. Patent No. 5,494,831). Each of the rejections is discussed in detail below.

### **I. The Claims are Novel**

The Examiner rejects Claims 1-4 and 11 as allegedly anticipated under 35 U.S.C. § 102(b) by Manautou *et al.* (U.S. Patent No. 3,875,013; hereinafter Manautou). The Applicants respectfully disagree. Nonetheless, in order to further the business interests of the Applicants, and without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG), and without waiving the right to prosecute the cancelled claims (or similar claims) in the future, the Applicants have amended Claim 1 to recite that the reaction site comprises a potassium iodide chromogen. Support for this amendment is found in the specification (See e.g., page 44, line 25-age 45, line 4), which describes the use of potassium iodide (KI) as a chromogen. Potassium iodide was found to provide a stable, detectable, colorimetric chromogen for use in the assay tests of the present invention. Manautou does not teach or suggest the use of potassium iodide as a chromogen in methods for detection of an analyte. As such, Manautou does not anticipate the presently claimed invention and the rejection should be withdrawn.

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<sup>1</sup> 65 Fed. Reg. 54603 (Sept., 8, 2000).

The Applicants have added new Claim 74, which recites that a color change occurs when ethanol concentration in saliva corresponds to a blood alcohol concentration of 0.04% and wherein substantially no color change occurs at ethanol concentrations below 0.04%. Support for such “on/off” type assays is provided in the specification, for example on page 45, lines 5-27.

## **II. The Claims are Non-Obvious**

The Examiner rejects Claims 5-6, 8-15, and 18-27 as allegedly obvious under 35 U.S.C. § 103(a) in light of Manautou *et al.* in view of Bogema (U.S. Patent No. 6,248,598; hereinafter Bogema) and Claim 7 as allegedly obvious under 35 U.S.C. § 103(a) in light of Manautou *et al.* in view of Kindler (U.S. Patent No. 5,494,831; hereinafter Kindler). The Applicants respectfully disagree. As described above, amended Claim 1 recites the use of potassium iodide as a chromogen. Neither Manautou, Bogema nor Kindler teach such an assay. As such, the cited references do not teach all of the elements of the claims as required for rejection under 35 U.S.C. 103 and the rejection should be withdrawn.

**CONCLUSION**

All grounds of rejection of the Final Office Action mailed 11/28/03 have been addressed and reconsideration of the application is respectfully requested. It is respectfully submitted that Applicants' claims as amended should be passed into allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

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